

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

TAMURA, Iwao  
9-22, Terauchi 1-chome  
Toyonaka-shi, Osaka 561 0872  
JAPON

**RECEIVED**  
NOV. - 6. 2006  
**TAMURA PATENT OFFICE**

Date of mailing (day/month/year) 26 October 2006 (26.10.2006)	
Applicant's or agent's file reference POKJ10411	IMPORTANT NOTIFICATION
International application No. PCT/JP2004/001048	International filing date (day/month/year) 03 February 2004 (03.02.2004)
Applicant OTSUKA CHEMICAL CO., LTD. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

EP, KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

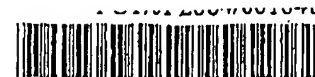
The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

**Translation**

PATENT COOPERATION TREATY



**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference POKJ10411	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/001048	International filing date (day/month/year) 03 February 2004 (03.02.2004)	Priority date (day/month/year) 04 February 2003 (04.02.2003)
International Patent Classification (IPC) or national classification and IPC C12P 19/28, C08B 37/00		
Applicant OTSUKA CHEMICAL CO., LTD.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>3</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 23 August 2004 (23.08.2004)	Date of completion of this report 10 December 2004 (10.12.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ The international application as originally filed/furnished
- ☒ the description:
- pages \_\_\_\_\_ 1, 3-18 \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ 2 \_\_\_\_\_ received by this Authority on \_\_\_\_\_ 23 August 2004 (23.08.2004)
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ the claims:
- pages \_\_\_\_\_ 2-6 \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ 1, 7-12 \_\_\_\_\_ received by this Authority on \_\_\_\_\_ 23 August 2004 (23.08.2004)
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_, as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

**2. Citations and explanations (Rule 70.7)**

Document 1: WO 03/008431 A1 (KAJIWARA Yasuhiro) January 30, 2003, page 15, lines 1-22 and page 16, line 25 to page 17, line 14

Document 2: Peptide Science, 1999, Vol. 1998, p. 153-156

Based on the description in Document 1, the inventions of claims 1-12 lack an inventive step.

Document 1 describes the production of sugar chain asparagine derivatives that are manufactured by a process described in *Biochimica et Biophysica Acta* (1997) Vol. 1335, No. 17, p. 23-32 wherein a protease/peptidase is added to the glycoproteins of defatted egg yolk, a lipid soluble protective group such as an Fmoc group, Boc group, allyl oxycarbonate group or acetyl group, etc., is introduced onto the sugar chain asparagine, and then separation is performed by separation chromatography utilizing a reverse phase column, for instance, ODS, phenyl-based, nitrile-based, or anion exchange-based column, and concretely, a monoQ column manufactured by Pharmacia, or an Iatro-beads column manufactured by Iatron. Document 1 also describes performing hydrolysis on the sugar chain asparagine to preliminarily cleave some of the sugar residues.

The invention described in Document 1 differs from the inventions of claims 1-12 only from the standpoint that a protease is not used in the process step of manufacturing a glycopeptide mixture from defatted egg yolk.

However, the production of a glycopeptide mixture from defatted egg yolk using a protease was a widely known, conventional means before the priority date of this application (if necessary, see JP 4-117393 A, JP 6-245784 A, or Toshitsu Symposium Koen Yoshishu (1993) 15th, p. 89-90). Therefore, persons skilled in the art can easily conceive of using a protease when producing the glycopeptide mixture from defatted egg yolk in the invention described in Document 1.

Based on the description in document 2, the inventions of claims 1-10 lack an inventive step.

Document 2 describes a process for producing sugar chain asparagine derivatives wherein a protease is added to glycoproteins from egg, an Fmoc group, which is a lipid soluble protective group, is introduced onto the sugar chain asparagine, and separation using reverse phase chromatography is performed.

Although document 2 does not state that glycoproteins are the substances obtained from defatted egg yolk using protease, because, as stated above, the production of glycoproteins from defatted egg yolk using proteases was a widely known, conventional means before the priority date of this application, utilizing a glycoprotein that was obtained from defatted egg yolk with a protease in the invention described in document 2 is merely a matter of conventional practice for persons skilled in the art.

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
-------------------------------	--------------------------------------	---------------------------------	---

WO 04/58984 A1

14.07.2004

24.12.2003

24.12.2002

[EX]

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure  
(day/month/year)Date of written disclosure  
referring to non-written disclosure  
(day/month/year)

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V:

Based on the description in Document 2, the inventions of claims 11 and 12 lack an inventive step.

When considering the efficiency of the reaction, etc., performing hydrolysis on the sugar chain asparagines to preliminarily cleave some of the sugar residues is merely conventional practice to persons skilled in the art.